

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
22-R-0030

CUSTOMER NO.  
178

FORM APPROVED  
OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

MERCK & COMPANY INC  
126 E LINCOLN AVENUE  
PO BOX 2000 RY80M-101  
RAHWAY, NJ 07065

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

See Attached Listing

FACILITY LOCATIONS/sites

RECEIVED

NOV 30 2006

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	125	789	1430	33	2252
5. Cats	0	0	0	0	0
6. Guinea Pigs	181	1472	456	50	1978
7. Hamsters	160	757	0	0	757
8. Rabbits	281	1787	1496	53	3336
9. Non-Human Primates	4428	298	1076	10	1384
10. Sheep	0	0	0	0	0
11. Pigs	0	18	0	0	18
12. Other Farm Animals					
Horses	0	4	0	0	4
13. Other Animals					
Ferrets	53	55	17	15	87
Cotton Rats	0	0	220	0	220
Gerbils	134	134	1954	0	2088
ASSURANCE STATEMENTS					2088

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

(b)(6), (b)(7)(c)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL

(b)(6), (b)(7)(c)

DATE SIGNED

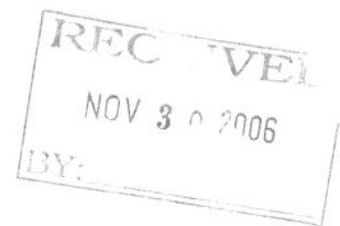
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(replaces VS FORM 18-23 (Oct 88), which

HEADQUARTERS

Q.092



Registration number 22-R-0030, November 29, 2006

A. Summary of exceptions to the regulations and standards:

One exception to the canine exercise program is to be reported. Fourteen dogs used in radioisotope labeled drug metabolism studies have been housed in special canine metabolism kennels in order to ensure safe and accurate collection of excreta for metabolite analysis. The housing provides 100% of the required floor space, but less than the required space for exercise. The period of time in this housing varies with the test compound, study and excretion rates. Most studies have lasted between 7-15 days, although two have lasted for 46 days. Positive human interaction has been greatly increased during this period. The protocol for the studies, which includes this exception, was approved by the IACUC.

B. General Column "E" Justification Statement:

Fifty guinea pigs experienced lethargy, ruffled fur and decreased appetite for 24-72 hours after IP injection of a compound for an IACUC approved procedure (General Safety Test, as described in 21 CFR 610.11). This is a compendial test required for release of a biologic product and administration of analgesic agents would compromise evaluation of the test results. The guinea pigs were monitored closely to see if the clinical signs would resolve. In all guinea pigs except five, all expected clinical signs resolved within the 24-72 hour time period. The five exceptions had increased pain and distress and were immediately euthanized.

Fifteen ferrets were studied according to an IACUC approved protocol for assessing (b)(4) Intermittent (b)(4) were induced by the administration of ar (b)(4) Commercially available analgesics could not be administered because they would confound interpretation of data and defeat the purpose of the research. The minimum number of animals was used to provide reliable data and the length of the study was limited to eight hours or less. The animals were observed continuously during the 8 hour period.

Twenty dogs were used in a (b)(4) for potential dog medication. The model was minimally invasive, requiring a short evaluation time, was localized to one (b)(4) and caused minimal clinical discomfort that began to dissipate after 4 hours and usually was gone by 8 hours. Administration of analgesics at less than 8 hours would compromise evaluation of the test results, but to the extent that discomfort persisted in some cases beyond 8 hours, analgesics were administered. The minimum number of animals was used on the model to still allow for the generation of useful data.

Thirteen dogs on an IACUC approved study developed unexpected acute terminal complications. The animals were closely monitored on the studies by the veterinary and research staff. The studies were conducted in accordance to FDA regulations as published in the Federal Register Vol. 59 No 183 September 1994, pages 48746 to 48752.

Three non-human primates developed unexpected acute terminal complications on an IACUC approved protocol. The animals were closely monitored on the studies by the veterinary and research staff. An additional seven non-human primates on safety assessment studies develop unexpected acute terminal complications. The studies were conducted in accordance to FDA regulations as published in the Federal Register Vol. 59 No 183 September 1994, pages 48746 to 48752.

Twenty-three rabbits on IACUC approved studies develop acute terminal complications. The animals were closely monitored on the studies by the veterinary and research staff. The studies were conducted in accordance to FDA regulations as published in the ICH guidelines (Federal Register 59, No. 183, Sept 22, 1994, pages 48746-48752 and Federal Register, Vol. 61, No. 67, April 5, 1996, pages 15360-15361).

Thirty rabbits were on an IACUC approved protocol to evaluate the efficacy of new (b)(4) compounds. The animals were (b)(4) and then treated with novel (b)(4) compounds. The interaction of pain relieving agents with novel compounds is unknown and could interfere with the study. The total number of rabbits was kept to the minimum required to produce meaningful and reliable test results. Additionally, the length of the study was limited to the time necessary to establish the model and conduct the studies.